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09/754,814	01/04/2001	Jean-Jacques Yaouanc	102.170A	3475

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[REDACTED] EXAMINER

EPPS, JANET L

ART UNIT	PAPER NUMBER
1635	11

DATE MAILED: 08/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/754,814

Applicant(s)

YAOUANC ET AL.

Examiner

Janet L. Epps

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 31 January 2002.

2a) This action is FINAL.                  2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-31 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-30 is/are rejected.

7) Claim(s) 31 is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)                  4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                  5) Notice of Informal Patent Application (PTO-152)  
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.                  6) Other:

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group IV, compounds, complexes, compositions, and methods of using said compounds, wherein said compound comprises a formula according to general formula (I), wherein A is a phosphorous atom, and R1 is selected from the a radical of formula (V) in Paper No. 10 is acknowledged. The traversal is on the ground(s) that, according to Applicants, the compounds of groups IV and VIII should be grouped together since they are substantially identical compounds with the sole exception of A being phosphorous or arsenic and it is deemed that these claims are substantially identical and are properly examined together since they have the same utility. This is not found persuasive because arsenic and phosphorous are two entirely different elements, having distinct structures and chemical properties. Additionally, for purposes of the initial restriction requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02. In the instant case, the invention of group IV is classified in 521/108, and the invention of group VIII is classified in 424/621. Therefore, the search for the invention of group IV is not required for the search of the invention of group VIII.

The requirement is still deemed proper and is therefore made FINAL.

2. Therefore, the invention of claims 1-31, will be examined to the extent that these claims read on compounds, complexes, compositions, and methods of using said compounds, wherein said compound comprises a formula according to general formula (I), wherein A is a phosphorous atom, and R1 is selected from the a radical of formula (V).

***Priority***

3. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

***Claim Objections***

4. Claim 31 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claim 31 has not been further treated on the merits.
5. Claim 15 is objected to because of the following informalities: Claim 15 recites the term “propylene,” it is likely that this term is misspelled, wherein the appropriate term is “propylene.” Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, and those claims dependent thereon, recites wherein R1 of general formula (I) is the radical of formula (V):  $(R_5O)_2-(P=O)-R_6$ . However, it is unclear which moiety of the radical

according to R1 of formula (V), is actually used to form a covalent linkage with A<sup>+</sup> of formula (I).

8. Claim 4 recites wherein the R5 lipid moiety is selected from the group consisting of “(i) and akyl group..., (ii) a cholesteryl derivative (iii) a perfluoro alkyl chain...” This group is vague and indefinite since the members recited in this group are not presented in alternative form.

9. Claim 5 recites wherein the R5 lipid moiety is selected from the group consisting of C<sub>14:0</sub>, C<sub>18:1</sub>, C<sub>18:2</sub> ; C<sub>15:0</sub>, C<sub>17:0</sub>, C<sub>17:1</sub>, C<sub>17:2</sub>.” The metes and bounds of this group are vague and indefinite since it is unclear how one particular R5 lipid moiety can consists of multiple lengths of carbon atoms. From the context of the elements of this group, it appears that the R5 lipid moiety can consist of C<sub>14:0</sub>, C<sub>18:1</sub>, and C<sub>18:2</sub> or C<sub>15:0</sub>, C<sub>17:0</sub>, C<sub>17:1</sub>, C<sub>17:2</sub>. The members of this group are not presented in alternative form.

10. Claim 6 recites wherein R2 and R4 represent each independently a radical selected from the group consisting of Ch3, C2H5, nC3H7, iso-C3H7., with n being an integer equal to 1, 2, or 3. This group is vague and indefinite since its members are no presented in alternative form. Moreover, the term the grammatical remarks recited in the term “iso-C3H7.” are also unclear.

11. Claim 13 recites the limitation “cholesteryl -[C(O)N-CH2-CH2-O],” however the formula of the moiety attached to the cholesteryl group is ambiguous since it is missing a left parenthesis in the formula.

12. Claim 14 recites the phrase “a perfluoroalkyl chain R6 is an ethyl group.” This phrase is vague and indefinite since, structurally speaking, it is clear that a perfluoroalkyl chain is not an ethyl group.

13. Claim 16 recites “-1,2 deoxyglycerol group.” The metes and bounds of the term “-1,2” recited in this chemical name is unclear.

14. Claims 22-25 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting an essential step, such omission does not set forth the method in clear and unambiguous terms. See MPEP § 2172.01.

Claims 22-23 recite a method for introducing *in vitro* a nucleic acid in a cell host. However, the method comprises only incubation steps, there is no step wherein it is clear that the nucleic acid is actually introduced into the cell host *in vitro*. The omitted step is a correlation, or recapitulation step at the end of the claim that restates the preamble.

Claims 24-25 recite a method for introducing *in vivo* a nucleic acid in cells of an host organism. However, the method comprises only incubation and administering steps, there is no step wherein it is clear that the nucleic acid is actually introduced into the cell host *in vivo*. The omitted step is a correlation, or recapitulation step at the end of the claim that restates the preamble.

***Claim Rejections - 35 USC § 102***

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1-4, and 7 are rejected under 35 U.S.C. 102(b) as being anticipate by Xu et al. (US Patent 5,852,198).

In the instant case, the art is applied to the extent that formula (I) recited in claim 1, encompasses wherein the R1 moiety (V) forms a covalent bond with A via the R6 group of formula (V).

Xu et al. teach compounds according the present invention, see for example, the compounds according to 4d, wherein R5 is an alky or alkenyl group, and R6 is a alkyl (-CH<sub>2</sub>-) or alkylene (-CH=) group, and wherein the anion is trifluoromethanesulfonate (see col. 2). In another embodiment the X anion, may represent a halide (see col. 2, line 16)

Xu et al. teach each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

17. Claims 1-2, 4, and 7 are rejected under 35 U.S.C. 102(b) as being anticipate by Xu et al.

Xu et al. teach compounds according the present invention, see for example, the compounds according to 4d, wherein R5 is an alky or alkenyl group, and R6 is a alkyl (-CH<sub>2</sub>-) or alkylene (-CH=) group, and wherein the anion is trifluoromethanesulfonate (see Scheme I, page 7698).

Xu et al. teach each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

Art Unit: 1635

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 8:30AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Janet L Epps, Ph.D.  
Examiner  
Art Unit 1635

JLE  
August 26, 2002